

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT MASSACHUSETTS**

BAGLY, *et al.*,

Plaintiffs,

v.

U.S. DEPARTMENT OF HEALTH
AND HUMAN SERVICES, *et al.*,

Defendants.

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Case No. 1:20-cv-11297-PS

**DEFENDANTS' REPLY IN SUPPORT OF MOTION TO DISMISS
PLAINTIFFS' AMENDED COMPLAINT**

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INTRODUCTION

Plaintiffs “cannot manufacture standing merely by inflicting harm on themselves based on their fears of hypothetical future harm.” *Clapper v. Amnesty Int’l*, 568 U.S. 398, 416 (2013). Plaintiffs must show “*immediacy and reality* to the allegations of future injury,” *Sea Shore Corp. v. Sullivan*, 158 F.3d 51, 59 (1st Cir. 1998) (quoting *O’Shea v. Littleton*, 414 U.S. 488, 497 (1974)) (emphasis added): “nonparanoid fear”—even fear that is “not fanciful, irrational, or clearly unreasonable”—is insufficient, *Clapper*, 568 U.S. at 416 (citation omitted). Even if a Health Care Provider or Advocacy Plaintiff could show actual concrete injury stemming from patient or client fears, those injuries would not be fairly traceable to the challenged federal regulations. Reasonable fear alone—as opposed to actual imminent injury—is not sufficient to establish standing when challenging legislative or administrative action. *Id.* at 417 n.7 (citing *Laird v. Tatum*, 407 U.S. 1, 10–14 (1972)). What is more, Plaintiffs’ “interests in enforcement” of Section 1557 by Defendants is insufficient to support their standing to challenge the 2020 Rule or any purported enforcement policy “because ‘a private citizen lacks a judicially cognizable interest in the prosecution or nonprosecution of another.’” *Diamond v. Charles*, 476 U.S. 54, 65 (1986) (quoting *Linda R.S. v. Richard D.*, 410 U.S. 614, 619 (1973)). These principles dispose of Plaintiffs’ arguments that they have standing to pursue their claims.

In *Washington v. U.S. Dep’t of Health and Human Servs.*, No. 2:20-cv-1105, 2020 WL 5095467 (W.D. Wash. Aug. 28, 2020), a plaintiff sought to invoke the jurisdiction of a federal court based on a theory of standing similar to Plaintiffs’ here. And that court correctly found that the plaintiff lacked standing to challenge all of the 2020 Rule’s provisions it challenged. *Id.* For the same reasons, Plaintiffs have failed show that they have standing and their claims should be dismissed.

Even assuming that Plaintiffs have standing to assert any claims, most of their claims are not ripe for review because they assume the meaning of generalized statutory or regulatory standards that have not been fleshed out in concrete cases. And Plaintiffs have failed to state a plausible equal protection claim or show that there is final agency action with respect to part of

Count IV; thus, these claims should be dismissed under Rule 12(b)(6) as well.

ARGUMENT

I. Plaintiffs Lack Standing

A. Plaintiffs' Characterizations of Article III's Requirements Are Immaterial

Because Plaintiffs are unable to present anything more than speculation that they will sustain imminent injury fairly traceable to each provision of the 2020 Rule they challenge, they seek refuge from Article III's standing requirements by quibbling over the proper language for analyzing imminence. ECF No. 27 at 8-9. To be sure, Plaintiffs can show that "injury is *imminent* . . . if the threatened injury is certainly impending or if there is a substantial risk that the harm will occur." *Massachusetts v. HHS*, 923 F.3d 209, 222 (1st Cir. 2019) (emphasis in original) (citation omitted). Whatever daylight realistically exists between those two standards, however, Plaintiffs "fall short of even [the latter one], in light of the attenuated chain of inferences necessary to find harm [from each challenged provision] here." *See Clapper*, 568 U.S. at 414 n.5 (concluding that similar chain of inferences does not establish a substantial risk of imminent injury).¹

The purpose of "[t]he 'imminence concept' . . . '[is] to ensure that the alleged injury is not too speculative.'" *Massachusetts*, 923 F.3d at 223. In *Massachusetts v. HHS*, preexisting state law provided "that qualifying residents . . . who lose contraceptive coverage would then be covered by [the state]." 923 F.3d at 218. The Plaintiff State challenged a regulation that "permitted employers with religious or moral objections to contraception to obtain exemptions from providing health insurance coverage to employees . . . for [certain] contraceptive care." *Id.* at 213. If employers took advantage of the exemption, the costs of coverage would fall directly on the Plaintiff State. Still, these facts alone were insufficient to establish standing without concrete evidence that specific Massachusetts employers were substantially likely to take advantage of the regulation's

¹ Although Plaintiffs purport to meet the imminence standard articulated in *Massachusetts*, 923 F.3d at 923, their arguments in support of standing are, at best, a thinly disguised effort to revive a standard that has been explicitly rejected—the "Second Circuit's 'objectively reasonable likelihood' standard." *See Clapper*, 568 U.S. at 410; *see also* ECF No. 22 at 9 (basing standing on "[i]ndividuals' reasonable fears of renewed healthcare discrimination").

exemptions. The First Circuit held that the plaintiff established standing only by “demonstrat[ing] that it [was] highly likely that at least three [specific] employers in the Commonwealth . . . will use the expanded exemptions,” and by “refer[ing] to data, which the [Defendants did] not contest,” showing that two of these entities employed a substantial number of people in the Commonwealth. *Id.* at 224. The First Circuit made clear that the inquiry needed to focus on women who would lose coverage based on the expanded exemptions, not women whose employers were denying contraceptive coverage “even before” challenged exemption was implemented. *Id.* at 224 n.9.

Plaintiffs “cite . . . two examples” (presumably their best ones) of what they claim are “the same chains of actions” as in *Massachusetts v. HHS*. ECF No. 27 at 9. Each example rightly recognizes that individuals cannot establish standing to challenge the 2020 Rule based solely on their own fear of possible future discrimination by health providers. *See City of Los Angeles v. Lyons*, 461 U.S. 95, 107 & n.8 (1983) (holding that fear of police misconduct, even when grounded in past injury, is not enough to demonstrate imminent threat: “It is the *reality* of the threat of repeated injury that is relevant to the standing inquiry, not the plaintiff’s subjective apprehension”); *Reddy v. Foster*, 845 F.3d 493, 502 (1st Cir. 2017) (“The complaint claims only that the plaintiffs ‘fear prosecution under the Act.’”). Fear alone is the antithesis of a concrete and particularized injury. *See Ernst & Young v. Depositors Econ. Prot. Corp.*, 45 F.3d 530, 548 (1st Cir. 1995) (“[P]resent fears are often less than horrible imaginings.”) (citation omitted). Apparently recognizing as much, Plaintiffs attempt to fasten additional allegations of injury onto each example. First, plaintiffs allege that fear may cause individuals to “spend time and money to identify providers that will provide non-discriminatory care.” ECF No. 27 at 9. And second, plaintiffs assert those same reasonable fears “will cause patients to seek out the services of Plaintiff Healthcare Facilities and Plaintiff Healthcare Advocates, who will suffer the financial and operational consequences of higher demand.” *Id.*

But the Supreme Court has held that injuries of these sorts are “not . . . fairly traceable to [the government] because they are based on third parties’ subjective fear.” *Clapper*, 568 U.S. at 417 n.7 (citing *Laird*, 407 U.S. at 10–14); *see also Equal Means Equal v. Ferriero*, No. 20-cv-

10015-DJC, 2020 WL 4548248, at *7 n.5 (D. Mass. Aug. 6, 2020).² As Judge Raggi explained in an opinion ultimately validated by the Supreme Court, had Plaintiffs’ theory of standing “only occurred to the plaintiff in *City of Los Angeles v. Lyons*, 461 U.S. 95 [], he presumably could have avoided the need to show an actual or imminent risk of being subjected to the challenged police chokehold procedure simply by moving from Los Angeles to Glendale, and then claiming that the actual injury of his moving costs was ‘fairly traceable’ to a not-irrational fear of a procedure to which he, after all, had already been subjected.” *Amnesty Int’l USA v. Clapper*, 667 F.3d 163, 180 (2d Cir. 2011) (Raggi, J., dissenting). But that is not the law. *See Clapper*, 568 U.S. at 416. (“[Plaintiffs] cannot manufacture standing merely by inflicting harm on themselves based on their fears of hypothetical future harm that is not certainly impending.”).³

Plaintiffs also cannot establish standing based on conclusory assertions that injuries “will occur” in the future. *See, e.g., Whitman-Walker Clinic Inc. v. U.S. Dep’t. of Health and Human Servs.*, No. 20-1630 (JEB), 2020 WL 5232076, at *18 (D.D.C. Sept. 2, 2020); *see also Sea Shore*, 158 F. 3d at 54 (citation omitted) (Courts “need not . . . ‘credit bald assertions.’”); *U.S. v. AVX Corp*, 962 F.2d 108, 117 (1st Cir. 1992) (“[Plaintiff] has not particularized these conclusory averments in any way.”). Citing *O’Shea v. Littleton*, 414 U.S. 488, 496 (1974), Plaintiffs claim that their “allegations about past conduct *can* be sufficient to allege an injury in fact from a risk that conduct will recur.” ECF No. 27 at 10. But “the holding in *O’Shea* [was] that past wrongs do

² Indeed, Plaintiffs’ “fear of discrimination”-based theory of standing is even less concrete and particularized than the theory rejected in *Clapper*, because Plaintiffs here do not even allege any “present costs and burdens” stemming from individuals’ fears. *See Clapper*, 568 U.S. at 416.

³ To be sure, “‘proximate causation’ is ‘not a requirement of Article III standing,’” ECF No. 27 at 16 n.7 (citation omitted), but that does not mean that any injury that is merely traceable in some way to government action will suffice. “The injury must be ‘fairly’ traceable to [each] challenged action,” a “term[that] cannot be defined so as to make application of the constitutional standing requirement a mechanical exercise,” but must incorporate “[t]he idea of separation of powers that underlies standing doctrine.” *Allen v. Wright*, 468 U.S. 737, 751, 759 (1984). Plaintiffs’ data breach or terrorist financing cases, ECF No. 27 at 30 n.12, have no bearing here because they do not involve the same “separation-of-powers principles” that bear on this case. *See Clapper*, 568 U.S. at 408. In those cases, no plaintiff asked a “court[] to oversee legislative or executive action.” *See Summers v. Earth Island Inst.*, 555 U.S. 488, 493 (2009).

not in themselves amount to that real and immediate threat of injury necessary to make out a case or controversy.” *Lyons*, 461 U.S. at 103. As the court in *Washington v. HHS* correctly explained with respect to a plaintiff’s challenge to the 2020 Rule’s religious exemption, Plaintiffs’ evidence “assumes the key premise—that healthcare providers or health insurers will refuse to provide services if the 2020 Rule’s religious exemption goes into effect. But [Plaintiffs] fail[] to identify any evidence in the record showing that it is [imminent] that [anyone] will refuse to provide services because of the 2020 Rule’s religious exemption.” *Washington*, 2020 WL 5095467, at *11.

To be sure, one link in a causal chain “demonstrat[ing] that a fiscal injury [to a plaintiff] is imminent due to the challenged federal regulation,” could be made concrete by reference to third parties’ “past litigating positions” if those positions make “it highly likely” that they will change a policy because of the regulation in a manner that clearly harms a plaintiff. *Massachusetts*, 923 F.3d at 222, 224. That is not the case here. Here, Plaintiffs point to “the challengers to the 2016 Rule in *Franciscan Alliance*, . . . includ[ing] an Illinois provider and [several] states.” ECF No. 27 at 11. But Plaintiffs have not shown that the 2016 Rule “forced” any of these entities “to change their policies.” *See id.* To the contrary, these entities obtained a preliminary injunction and ultimately partial vacatur of the 2016 Rule, *see Franciscan Alliance v. Burwell*, 227 F. Supp. 3d 660 (N.D. Tex. 2016), “which allowed them to effectively avoid [any] obligation to” change their policies in light of the 2016 Rule. *See Massachusetts*, 923 F.3d at 224 n.9. Because these entities “likely” had policies Plaintiffs dislike “even before the [2020 Rule],” Plaintiffs cannot rely on them in their purported chain of inferences that causes injury “due to the challenged federal regulations.” *See id.* at 222, 224 n.9; *see also id.* at 224 (explaining that it was appropriate to “exclud[e] previously exempt” employers from the causation analysis). In other words, it is implausible that patients related to the *Franciscan Alliance* plaintiffs are likely to “turn[] to [Plaintiff Healthcare Facilities and Advocates] for services *because of the [2020] Rule*,” *see* ECF No. 27 at 12 (emphasis added), when Plaintiffs have provided no indication that the *Franciscan Alliance* plaintiffs have changed any policy or practice as a result of the 2020 Rule or plan to do

so.⁴ *See Massachusetts*, 923 F.3d at 222. And even if these entities did change their policies, Plaintiffs provide no more than speculation that any affected individuals would turn to Plaintiffs for services.

Plaintiffs appear to base their chain of causation at least in part on the suggestion that, because Plaintiffs hail from around the country, aggregately, they have numerous potential patients or potential clients who could turn to them for services. Thus, plaintiffs urge, they need not particularize their conclusory allegations; rather, the Court should presume standing to challenge the 2020 Rule because it is likely that *someone* will be injured because of the Rule and that person might turn to one of the Plaintiffs for services. *See, e.g.*, ECF No. 27 at 12 (“Plaintiff Healthcare Facilities and Healthcare Advocates will have to expend resources so long as *any* client or patient turns to them for services because of the [2020] Rule.”). But “the doctrine of standing to sue is not a kind of gaming device that can be surmounted merely by aggregating the allegations of different kinds of plaintiffs, each of whom may have claims that are remote or speculative taken by

⁴ Plaintiffs cite two briefs that they claim reflect policy changes caused by the 2020 Rule. ECF No. 27 at 11. Even assuming Plaintiffs could manufacture standing by scouring Westlaw and then asserting that they will be affected by whatever policy changes are arguably out there, a close look at the cited materials indicates that the referenced policies were not changed or likely to change due to the 2020 Rule. What is more, Plaintiffs have not demonstrated here that the policies challenged in those cases were prohibited under the 2016 Rule or permitted by the 2020 Rule. The 2016 Rule prohibited “categorical coverage exclusions or limitations for *all* health services related to gender transition,” but permitted covered entities to “determin[e] . . . whether a particular health service is medically necessary or otherwise meets applicable coverage requirements in any individual case.” 81 Fed. Reg. at 31,472 (inserting 45 C.F.R. §§ 92.207(b)(4), 92.207(d)) (emphasis added). In the Arizona case, for example, defendants argue that the surgery sought by plaintiffs is not “medically appropriate . . . for [plaintiffs] in particular,” but point out that they *do* offer health services related to gender transition—“hormone treatments and behavioral health/counseling,” making their policy arguably lawful under the 2016 Rule. *D.H. v. Snyder*, No 4:20-cv-335-SHR (D. Ariz. Sept 28, 2020), ECF No. 18 at 2-3. On the other hand, plaintiffs in that case argue that even if the 2020 Rule were not partially enjoined, defendants’ policy is not valid because “the ACA prohibits discrimination based on sex, which,” they argue, “encompasses discrimination based on transgender status” based on the “plain text of Section 1557.” *Id.*, ECF No. 25 at 7-8 (D. Ariz. Oct. 26, 2020). Plaintiffs have failed to show that anything in these cases suggests that they face imminent harm *due to the 2020 Rule*. *See Massachusetts*, 923 F.2d at 222. At a minimum, these cases demonstrate why this matter is not ripe for review, *see infra* at 15–18; this Court must abstain from adjudicating this case based on a causal chain of injury that requires it to adjudicate the outcome of other, pending concrete cases.

themselves.” *Pub. Citizen, Inc. v. NHTSA*, 489 F.3d 1279, 1294 (D.C. Cir. 2007) (Kavanaugh, J.,) (quoting *ASARCO Inc. v. Kadish*, 490 U.S. 605, 615–16 (1989) (opinion of Kennedy, J.)). “[T]he law of averages is not a substitute for standing.” *Id.* (quoting *Valley Forge Christian College v. Ams. United for Separation of Church and State, Inc.*, 454 U.S. 464, 489 (1982)).

Defendants do not dispute that standing can exist where the chain of causation “includes a third party’s actions,” ECF No. 27 at 12, but “[w]hen . . . a plaintiff’s asserted injury arises from the government’s allegedly unlawful . . . lack of regulation[] of *someone else* much more is needed,” see *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 562 (1992) (emphasis in original). Plaintiffs assert that they can bypass the need to demonstrate that the “several ‘links’” in their chain “are not hypothetical or tenuous,” *California v. Azar*, 911 F.3d 558, 572 (9th Cir. 2018), by relying on *Department of Commerce v. New York*, where the Court found that third parties were likely to react “in *predictable* ways,” ECF No. 27 at 13 (emphasis in original) (quoting *Dep’t. of Commerce v. New York*, 139 S. Ct. 2551, 2566 (2020)). But Plaintiffs’ causal links are different in kind.

Plaintiffs assert that, in light of the 2020 Rule, insurers will “forgo covering gender-affirming care” because “it costs insurers money to reimburse healthcare providers for the costs of providing gender-affirming care.” ECF No. 27 at 14. But “predicting future injury and the behavior of third parties is usually suspect.” See *Sea Shore*, 158 F.3d at 56. Many insurers may, for example, decide not to categorically drop all coverage of gender conforming care due to demand or concerns about public relations—a prediction perhaps more plausible than Plaintiffs’ as it accords with “the basic laws of economics,” see *Sea Shore*, 158 F.3d at 56 (citation omitted), while Plaintiffs’ does not. The point is simply that Plaintiffs’ suggestion that insurers will forgo covering gender-affirming care is far from predictable. In any event, to establish standing, insurers must have modified their gender-affirming coverage provisions *due to the 2020 Rule*, see *Massachusetts*, 923 F.3d at 222, 224 n.9, but the 2020 Rule “makes no changes to what has been the status quo since December 2016, when [HHS] was enjoined from enforcement of the gender identity provisions of the 2016 Rule; such provisions have now been vacated by a court. Any recent decrease in blanket

exclusions for sex-reassignment coverage is therefore more likely to be attributable to health insurance issuer or plan sponsor choice.” 85 Fed. Reg. 37,160, 37,199 (June 19, 2020). These facts cast further doubt on the predictability of Plaintiffs’ purported harm. *See* AVX, 962 F.2d at 114 (citation and alteration omitted) (“Empirically unverifiable conclusions, not logically compelled, or at least supported, by the stated facts, deserve no deference.”). Plaintiffs have not established that any insurer providing coverage to Plaintiffs’ present or future patients or clients has changed, or will imminently change, its policies in light of any challenged provision of the 2020 Rule.

Further, HHS never “recognize[d] that some entities *will* make changes” to policies due to the 2020 Rule. ECF No. 27 at 15 (emphasis added) (citing 85 Fed. Reg. at 37,225). HHS actually said “that because the gender identity provisions of the 2016 Rule have been vacated prior to this rule being finalized, it is even less likely than at the time of the proposed rule that this final rule will lead to changes in policies and procedures concerning gender identity.” 85 Fed. Reg. at 37,225. To the extent any other statement in the preamble suggests that covered entities *might* change their policies because of the 2020 Rule, that “kind of off-handed speculation—which was in no way particular to . . . the particular [people] on which [Plaintiffs] base[their] standing arguments, . . . does not measure up to the kind of [statement] courts have relied on to find standing.” *Washington*, 2020 WL 5095467, at *9. *Compare* 85 Fed. Reg. 37,255 with *Massachusetts*, 923 F.3d at 224-35.

B. Plaintiffs Lack Standing to Challenge Any Provision of the 2020 Rule

(1) *The repeal of the definition of “on the basis of sex.”* As an initial matter, the heading in Plaintiffs’ brief suggests that they claim injury not only from the challenged regulation, but also HHS’s purported “unlawful interpretation of [the] term” “sex” in the preamble to the rule. *See* ECF No. 27 at 17; *see also id.* at 25–26. But it is well-established that, when challenging agency action, “neither [a] decision’s legal reasoning nor the precedential effect of such reasoning confers standing unless the substance of the [challenged] decision itself gives rise to an injury in fact.” *New England Power Generators Ass’n v. FERC*, 707 F.3d 364, 369 (D.C. Cir. 2013). Nor can an agency’s mere statutory interpretation outside of a binding rule, standing alone, be “subject to judicial review unless it is relied upon or applied to support an agency action in a particular case”

because, unlike a legislative rule itself, it “does not carry the force of law.” *Am. Tort Reform Ass’n v. OSHA*, 738 F.3d 387, 390, 393 (D.C. Cir. 2013). A “regulatory preamble . . . is not legally binding,” *Peabody Coal Co. v. Director, Office of Workers Compensation Progs.*, 746 F.3d 1119, 1125 (9th Cir. 2014), and it is “well-established that a regulatory preamble is incapable of altering regulatory text’s plain meaning,” *Gustavsen v. Alcon Labs., Inc.*, 903 F.3d 1, 13 (1st Cir. 2018); *see also Wyeth v. Levine*, 555 U.S. 555, 575–77 (2009).

Reflecting a number of the errors already discussed, Plaintiffs also say that Mr. Lazor has standing based only on past discrimination in healthcare, ECF No. 27 at 17. But “past wrongs do not in themselves amount to that real and immediate threat of injury necessary to make out a case or controversy” for prospective relief, *Lyons*, 461 U.S. at 10. And Plaintiffs suggest that Mr. Lazor’s unnamed local hospital may be reverting to discriminatory practices in light of the 2020 Rule, but without any allegations indicating *why* any such change has happened or is imminent *due to the rule*. ECF No. 27 at 18. Thus, one cannot determine the “*reality* of the threat of repeated injury” as opposed to Mr. Lazor’s “subjective apprehensions.” *Lyons*, 461 U.S. at 107 n.8; *see also Clapper*, 568 U.S. at 416. Indeed, Plaintiffs “make no effort to explain why [the hospital] would be willing to risk revising [its] practices or policies to discriminate against [Mr. Lazor] in light of the Supreme Court’s guidance in *Bostock* and the very arguments [Plaintiffs] advance[] in this case”—that the plain meaning of “sex” includes LGBTQ discrimination. *Washington*, 2020 WL 5095467, at *8.

Some Plaintiffs assert that they have organizational standing to challenge HHS’s decision not to define “sex” in the 2020 Rule, *see* ECF No. 27 at 18-22, but organizational standing requires them, “‘like an individual plaintiff, to show actual or threatened injury in fact that is fairly traceable to the alleged illegal action and likely to be redressed by a favorable court decision,’” *Food & Water Watch, Inc. v. Vilsack*, 808 F.3d 905, 919 (D.C. Cir. 2015) (citation omitted);⁵ they cannot “secure

⁵ Plaintiffs misconstrue a statement from *Lujan* in an attempt to bypass the three-part test for Article III standing. *See* ECF No. 27 at 18, 36. The principle to which Plaintiffs refer applies only to “cases involving claims of threatened injury emanating directly from governmental conduct,” but in this “setting[,] . . . in which the government acts [or does not act] directly against a third

. . . standing simply by making an expenditure based on a nonparanoid fear,” *Clapper*, 568 U.S. at 416. They assert, without particularizing their averments in any way, that the “rule will increase demand for their medical services, straining their resources.” ECF No. 27 at 18; *see also id.* at 21. But “[t]o the extent that such assertions are based on anything other than conjecture, . . . they do not establish injury that is fairly traceable to [the 2020 Rule] because,” as Plaintiffs admit, “they are based on third parties’ subjective fear[s]” of the Rule’s impacts, not HHS’s decision not to define “sex” by rule itself.⁶ *See Clapper*, 568 U.S. at 417 n.7; *see also* ECF No. 27 at 19 (“fear of discrimination” will cause injuries); *id.* at 9 (“fears will cause” injuries).⁷

party, whose expected response in turn will injure the plaintiff[, t]he standing question . . . frequently turns . . . on so-called causation issues.” *See Wilderness Soc. v. Griles*, 824 F.2d 4, 11 (D.C. Cir. 1987). And “personal injury . . . usually depends upon how likely it is that the third party’s response to the challenged governmental action will injure the plaintiff *at all*.” *Id.* at 12; *see also Lujan*, 504 U.S. at 562 (when purported injuries stem from the “government’s allegedly unlawful . . . lack of regulation of *someone else*, much more is needed”).

⁶ Plaintiffs submitted thirteen declarations in opposition to the motion to dismiss. The closest any of them come to substantiating a claim that any entity is changing a policy in light of the 2020 Rule is an allegation that “UnitedHealthcare Community Plan recently issued a policy bulletin announcing the retirement of a treatment policy for gender dysphoria in Louisiana.” ECF No. 27-7 ¶ 13. But the bulletin, which Plaintiffs attach, was issued *before* the 2020 Rule became effective. *See id.* at 15. And Plaintiffs admit that this filing is unlikely to be a policy change at all, as opposed to a technical regulatory filing. *See id.* ¶ 13 (“One of our Medicaid Eligibility Specialists has sought out more information about this change from status officials *and has been told no change has been made.*”) (emphasis added). Even if Plaintiffs had established a policy change due to some part of the 2020 Rule, it is far from clear that any UnitedHealthcare subscribers in Louisiana would default to CrescentCare in the same way as Massachusetts residents to the state in *Mass. v. HHS*. *See* 923 F.3d at 225–26 (discussing calculations showing the likely number of women that would lose coverage and qualify for state programs).

⁷ Some Plaintiffs assert that they have third-party standing, on behalf of their patients, to challenge HHS’s decision not to define “sex” by rule, *see* ECF No. 27 at 20–21. But even if any Plaintiff meets one of the exceptions to the prohibition on third-party standing, that cannot substitute for the three-part test for Article III standing. The prohibition on third-party standing is an *additional* prudential limitation that exists “even when the plaintiff has alleged injury sufficient to meet the ‘case or controversy’ requirement.” *Warth v. Seldin*, 422 U.S. 490, 499 (1975); *see also United Food and Commercial Workers Union Local 751 v. Brown Grp. Inc.*, 517 U.S. 544, 551, 557 (1996) (explaining that the prudential requirements “[s]upplement[] the[] constitutional requirements”). Thus, no Plaintiff can rely on their arguable satisfaction of the exceptions to third-party standing doctrine as a substitute for their independent establishment of Article III standing.

What is more, “an organization must allege that the defendant’s conduct perceptibly impaired the organization’s ability to provide services,” which occurs “when the defendant’s conduct causes an inhibition of the organization’s daily operations,” *Food & Water Watch, Inc.*, 808 F.3d at 919 (citation omitted), which Plaintiffs have not shown here. That an organization might “spend resources educating [their] members and the public” does not “indicate[] that [any] organizational activities have been perceptively impaired in any way.” *Id.* at 921; *see also Keep Chi. Livable v. City of Chi.*, 913 F.3d 618, 625 (7th Cir. 2019) (“contention of injury” that organization finds “it difficult to . . . educate on home-sharing in Chicago before a court rules on . . . [its] challenges to the constitutionality of a [challenged] Ordinance” is “little more than a ‘mere interest in a problem’”); *Washington*, 2020 WL 5095467, at *10 (administrative costs incurred to educate public insufficient because any plaintiff could “manufacture standing any time it wanted to challenge an agency regulation by expressing a desire to incur administrative costs as a result of the challenged regulation”); *Boston’s Children First v. Boston Sch. Comm.*, 183 F. Supp. 2d 382, 403 (D. Mass. 2002) (rejecting standing “argu[ment] that [plaintiff] has ‘expended considerable resources in providing counseling and information to its members and [the] general public about the challenged . . . policy’”).

Plaintiff Equality California lacks associational standing because its members lack standing for the same reasons as Mr. Lazor. *See supra* at 9. Plaintiffs assert that reviving the encumbered 2016 rule’s definition of “sex” as opposed to relying on the plain meaning of the underlying statute would redress their injuries without explaining how. ECF No. 27 at 24. Plaintiffs say that this Court could “*require* HHS to enforce Section 1557” in a particular way, *id.*, but it is well-established that Plaintiffs’ “interests in enforcement” of Section 1557 do not provide them standing to sue HHS to pursue an abstract interpretation; Plaintiffs “could not compel [HHS] to enforce [their interpretation] against [anyone] because ‘a private citizen lacks a judicially cognizable interest in the prosecution or nonprosecution of another.’” *Diamond v. Charles*, 476 U.S. 54, 64 (1986) (quoting *Linda R.S. v. Richard D.*, 410 U.S. 614, 619 (1973)). Whether, how, and to what extent HHS would enforce the 2016 Rule, partially vacated by the *Franciscan Alliance*

court, if this Court were to vacate HHS’s decision not to define “on the basis of sex” in the 2020 Rule, is entirely speculative. *See Heckler v. Chaney*, 470 U.S. 821, 831–32 (1985) (discussing “the many variables involved” and factors considered when agencies make enforcement decisions).⁸

Plaintiffs argue that this Court could redress their purported injury by replacing a rule that does not define “sex” with a rule that defines the term to include some, but not all, of the types of discrimination they believe it encompasses based apparently on the presumption that HHS’s qualified interpretation in the preamble has legal effect. ECF No. 27 at 24. Plaintiffs’ reliance on the preamble language must be ignored because, as explained *supra*, at 8–9, they must establish an injury caused by the provisions of the 2020 Rule they seek to challenge, not the preamble. Because vacating an agency statement is not a remedy available to this court, *see supra* n.8, their redressability argument is confusing, to say the least. To be sure, only a reduction in injuries is required for redressability, *see* ECF No. 27 at 24–25, but redressability is contingent upon a concrete and particularized injury. Only because Plaintiffs seek to invoke the jurisdiction of this Court by way of abstract injuries is it easy for them to make conclusory claims that reviving some of the prior rule’s definitional language will redress some of those injuries.

(2) *Scope of the Definition of Health Program or Activity.*⁹ Plaintiff Healthcare Facilities and Healthcare Advocates continue to premise their standing to challenge this definition on speculation that their future patients’ health insurers will change their policies in a manner that

⁸ In APA cases district courts have “jurisdiction only to vacate the [agency’s] decision” and have “no jurisdiction to order specific relief.” *Palisades Gen. Hosp. v. Leavitt*, 426 F.3d 400, 403 (D.C. Cir. 2005) (quoting *Cty. of Los Angeles v. Shalala*, 192 F.3d 1005, 1011 (D.C. Cir. 1999)).

⁹ Because the 2020 Rule’s revision of the scope of federal entities governed by Section 1557 involves an interpretation of different statutory language than the 2020 Rule’s revision of the scope of other entities governed by Section 1557’s term “health program or activity,” the legal theories governing each challenge differ, and, contrary to Plaintiffs’ arguments, *see* ECF No. 27 at 26 n.11, Plaintiffs must establish standing for this Court to address each one independently. *See DaimlerChrysler Corp. v. Cuno*, 547 U.S. 332, 353 (2006); *Steel Co. v. Citizens for a Better Environment*, 523 U.S. 83, 94 (1998). The issue is whether adjudicating the issues involve different legal claims, not whether they are different “provisions.” *See* ECF No. 27 at 26 n.11. In any event, the changes *are* encompassed in two different “provisions”: one codified at 45 C.F.R. § 92.3(a)(2), and the other at 45 C.F.R. § 92.3(b),(c). Nothing in *FW/PBS, Inc. v. City of Dallas*, 493 U.S. 215, 233–36 (1990) says otherwise.

harms them due to the 2020 Rule, ECF No. 27 at 27–28, which as explained *supra* at 7–8, is not predictable. BAGLY claims that it will increase administrative costs “to sort out which out-of-state patients have coverage for the gender-affirming care they obtain through BAGLY, now that there is no standard federal mandate of coverage,” ECF No. 27 at 27–28, but there was no gender-affirming care standard mandate of coverage before the 2020 Rule. *See supra* n.4. The prior rule prohibited only categorical exclusions of all health services related to gender transition, not specific federal standards for gender affirming care. *See id.* Accordingly, BAGLY cannot plausibly contend it faces a substantial likelihood of a discernable increase in administrative costs due to this portion of the 2020 Rule. For the same reasons, the allegations by Plaintiffs Campaign for Southern Equality and Transgender Emergency Fund that they will incur increased costs related to assisting clients seeking gender-affirming care have no relationship to the 2020 Rule. *See* ECF No. 27 at 28.

(3) *Scope of federal entities covered by Section 1557.* Plaintiffs assert that Plaintiff Indigenous Women Rising (“IWR”)’s “injury is pregnancy discrimination against the Native people that IWR serves” from the Indian Health Service (“IHS”). ECF No. 27 at 29. But Plaintiffs continue to provide no basis for why IHS’s purported discrimination against anyone is imminent, let alone substantiated the other links in their causal chain, choosing instead to rely on insufficient allegations about past discrimination. *See supra* at 4–5. And Plaintiffs appear to misunderstand Defendants’ point that, because both the Equal Protection Clause and the 2016 Rule prohibited IHS from engaging in discrimination, it is even more speculative that IHS will begin discriminating now that it is subject to only one. *See* ECF No. 27 at 30.

(4) *Legal Standards for Enforcing Section 1557.* That it might be “more difficult for Plaintiffs’ patients and clients to bring claims of intersectional discrimination” because of these changes, ECF No. 27 at 30, is not a concrete or particularized injury but “an impermissible ‘generalized grievance’ [that is] inconsistent with ‘the framework of Article III’ because ‘the impact on [plaintiffs] is plainly undifferentiated and common to all members of the public.’” *Lujan*, 504 U.S. at 575 (quoting *United States v. Richardson*, 418 U.S. 166, 171, 176–77 (1974)).

Plaintiff Healthcare Facilities and Advocates assert only an abstract injury—greater “difficult[y] . . . help[ing] assert patient rights under Section 1557 and [to] obtain redress” for speculative future discrimination, *see* ECF No. 27 at 31; *see also id.* at 32—“[un]anchored in any relevant particulars”—which is insufficient to establish standing. *AVX Corp.*, 962 F.2d at 117. Also, “an organization’s use of resources for litigation . . . is not sufficient to give rise to an Article III injury.” *Food & Water Watch*, 808 F.3d at 919.

(5) *Religious and abortion exemptions; association discrimination.* Plaintiffs admit that their alleged injuries with respect to these provisions are “grounded [only] in Plaintiffs’ and their patients’ own past experiences,” ECF No. 27 at 34 (exemptions); *see also id.* at 35–36 (associational discrimination), which, again, is insufficient, *see supra* at 4–5; *see also Washington*, 2020 WL 5095467, at *11 (“[Plaintiffs] failed to identify any evidence in the record showing that it is [imminent] that [their imminent future patients’ or clients’ current] healthcare providers or health insurers will refuse to provide services if the 2020 Rule’s religious exemption goes into effect.”).¹⁰ What is more, to the extent Plaintiffs ground their injury in patients’ nonparanoid “fear [of] discrimination at the hands of religiously affiliated providers,” ECF No. 27 at 33 (citation omitted), that injury is not fairly traceable to the challenged regulation for the reasons described *supra* at 3–4.

(6) *Notice and Taglines.* Plaintiffs assert standing based on nothing but speculation that the 2020 Rule’s modifications “will cause patients who unsuccessfully seek care elsewhere because of communication difficulties to come to Plaintiff Healthcare Facilities.” ECF No. 27 at 37. But

¹⁰ One declarant appears to speculate that Ascension Health, a large Catholic health care system, might adopt discriminatory policies due to the 2020 Rule that might end up having some impact on CrescentCare. *See* ECF No. 27-12 ¶ 21. But the declarant does not cite an actual policy change by Ascension Health, instead citing a general statement that “the health ministries of Ascension will only provide care and procedures consistent with the values that are constitutive of our organization and its facilities as ministries of the Catholic Church.” *Id.* (citation omitted); *see also id.* ¶ 22. This Court should reject Plaintiffs’ invitation to “make a judgment about church doctrine” in “order to probe” any possible impact of that statement on Plaintiff CrescentCare in light of the 2020 Rule. *See Hosanna-Tabor Evangelical Lutheran Church and Sch. v. EEOC*, 565 U.S. 171, 205 (2002) (Alito, J., concurring).

“[s]imply asserting, without any elaboration, that individuals will” come to Plaintiffs’ facilities “does not ‘suffice[]to demonstrate the substantial probability’ that discrimination will actually occur as required to establish standing.” *Whitman-Walker*, 2020 WL 5232076, at *18 (citation omitted). Plaintiffs’ assertion is premised on layer upon layer of speculation. First, it is premised on speculation about the 2020 Rule’s effect on limited English proficiency (“LEP”) populations. With respect to LEP, the 2020 Rule, among other things, removed a requirement that covered entities provide certain notice and taglines in the top fifteen languages spoken in each state regardless of the size of the state or the demographics of a covered entity’s patients. The flexibility allowed by the 2020 Rule permits more innovative approaches to cost effectively serving these populations without resulting in discrimination or barriers to care. Plaintiffs also provide nothing but speculation that, assuming some covered entities might change their notices and taglines, individuals receiving those notices and taglines would for some reason rush to Plaintiffs’ facilities for care. What is more, Plaintiffs’ reasoning depends on the assumption that these individuals would so predominantly lack insurance that their care would be, in the aggregate, “non-reimbursable” and result in more costs than revenue. ECF No. 27 at 37. But there is no reason to believe that this would be the case. And Plaintiffs ignore the requirements of applicable state law.

(7) *Conforming Amendments to Related Regulations*. Again, Plaintiffs simply assert in their brief without elaboration that other changes in the 2020 Rule “will cut into [Plaintiffs’] budgets.” ECF No. 27 at 37. Such an assertion “is not anchored in any relevant particulars.” *AVX Corp.*, 962 F.2d at 117. *See Whitman-Walker*, 2020 WL 5232076, at *18.

II. Plaintiffs Have Failed to Establish that the Generalized Regulatory Standards under Section 1557 or the 2020 Rule are Ripe for Review

Plaintiffs assert that the scope of Section 1557’s nondiscrimination requirements are fit for review because “[t]his is a challenge to an already promulgated regulation . . . [and] Defendants admit . . . this is a ‘purely legal’ challenge.” ECF No. 27 at 38–39. But even when “there can be no question that [a] regulation—promulgated in a formal manner after notice and evaluation of submitted comments”—is the subject of judicial review and the issue a plaintiff raises “presents a

purely legal question,” the “legal issue as presently framed [may] not [be] appropriate for judicial resolution,” *Toilet Goods Ass’n v. Gardner*, 387 U.S. 158, 162-63 (1967), especially “where the agency retains considerable discretion to apply the new rule on a case-by-case basis,” *Sprint Corp. v. FCC*, 331 F.3d 952, 956 (D.C Cir. 2003).

Plaintiffs’ primary response is an erroneous assertion that Defendants’ “arguments are . . . merits arguments.” ECF No. 27 at 39. But instead of explaining how the rule that they challenge (as opposed to its preamble), is ripe for review, *they* just switch to the merits, asserting that it is implausible that “Defendants truly adopted no interpretation at all [because the 2020] Rule would [then] be the definition of arbitrary.” ECF No. 27 at 39. In response to Defendants’ point that adjudication may establish that the 2020 Rule covers the very type of discrimination Plaintiffs fear it does not cover, *see* ECF No. 22 at 29, Plaintiffs simply assert that this “goes to the merits, whether Defendants acted arbitrarily in deleting the definition.” ECF No. 27 at 39. But the fact that adjudication may establish the scope of the definition of “sex” to be broad is precisely why their claims are unripe; it has nothing to do with Defendants’ reasons for removing the explicit definition from the code of federal regulations.

Plaintiffs claim that unlike *Aulenback, Inc. v. Fed. Highway Admin.*, 103 F.3d 156 (D.C. Cir. 1997), the preamble to the final rule “explains Defendants’ interpretation of Section 1557.” *See* ECF No. 27 at 39. Of course, the *Aulenback* plaintiffs claimed that the challenged policy provided an interpretation of a statute the agency implemented, 49 U.S.C. § 521(b)(5)(A). *See* 103 F.3d at 159, 164. Plaintiffs assert that the preamble here is “authoritative” while the *Aulenback* policy was not. ECF No. 27 at 39. But in *Aulenback*, the Court “assum[ed] the [agency] ha[d] the policy” in the Manual, but did not find it to be “authoritative” because “petitioners failed to show on the record before the court that [the agency] ha[d] purported to take an enforcement action based on the Manual’s definition” of the statutory term. *Id.* In other words, an interpretation is not ripe for review unless it appeared in a binding rule or has been established by case-by-case adjudication. *See id.* Moreover, the *Aulenback* plaintiffs never “ask[ed] the [agency] for its interpretation of the Manual” before rushing to court. *Id.* at 167. Here, even though the preamble

explained that “the elimination of a regulatory definition of [a] term would not preclude application of the [Supreme] Court’s construction,” 85 Fed. Reg. at 37,168, Plaintiffs similarly never asked HHS for its interpretation of Section 1557 in light of *Bostock* before immediately rushing to court. Plaintiffs say that here “there is an administrative record on which to assess the rule’s legality.” ECF No. 27 at 39. But there is no reason that there would not have likewise been an administrative record supporting the agency’s creation of the Manual at issue in *Aulenback*.

Plaintiffs incorrectly contend that this case is ripe for review both because the Rule “is unlawful and harms them now” and because of “the possibility that it may also harm other future plaintiffs.” ECF No. 27 at 39-40. Defendants dispute that the Rule is currently harming Plaintiffs. But even assuming it is, Plaintiffs’ injuries must be related to some *future* discrimination by third parties that they believe will violate Section 1557. Thus, if and when any such discrimination does occur, these very Plaintiffs in this case (if they can establish third-party standing), not “other, future plaintiffs,” *see id.* at 40, can step in to assert that the discriminatory conduct violates Section 1557 without this Court taking any action right now at all.¹¹ *See McInnis-Misenor v. Me. Med. Ctr.*, 319 F.3d 63, 72-72 (1st Cir. 2003).

Plaintiffs are wrong to say that Defendants’ arguments “would insulate from judicial review *any* decision to delete regulatory protections.” ECF No. 27 at 40. Ripeness doctrine insulates from judicial review generalized regulatory standards unless and until the regulation directly and actually affects the “primary conduct” of a regulated entity. *See Toilet Goods*, 387 U.S. at 164; *see also Lujan v. Nat’l Wildlife Fed.*, 497 U.S. 871, 891 (1990); *Sprint Corp.*, 331 F.3d at 956. The cases Plaintiffs cite involved clear direct and immediate effects. For example, in *Motor Vehicle Mfrs. Ass’n of U.S. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 38 (1983), the agency permitted cars to be manufactured without passive restraint seat belts as soon as the rule became effective. The agency did not replace the rule with a generalized standard that might

¹¹ This is precisely why, even assuming Plaintiffs have an Article III injury, they cannot plausibly establish hardship from delay—unless and until any of the purported discrimination that Plaintiffs assert is so predictable actually occurs, they cannot plausibly bear any substantive injury.

someday be interpreted to require passive restraints. *See id.*; *see also Dep't of Homeland Sec. v. Regents of the Univ. of Cal.*, 140 S. Ct. 1891, 1910 (2020) (revoking “work authorization and . . . benefits” from “[s]ome 700,000 aliens”).

III. Counts III and IV Should be Dismissed under Rule 12(b)(6)

A. Plaintiffs Have Not Pleaded a Plausible Equal Protection Claim

Plaintiffs do not dispute that “the rule in this circuit [is] that classifications on the basis of sexual orientation or transgender status are subject to rational basis scrutiny,” *see* ECF No. 22 at 31 n.6 (and cases cited therein), and all of their allegations related to their equal protection claim purport to be facts that “evinced[] animus toward transgender people,” Am. Compl. at 94, ECF No. 18. Plaintiffs then misstate the applicable rational basis standard, *see* ECF No. 27 at 41 n.15, because their claim cannot survive the proper standard: that only actions “inexplicable by anything but animus toward the class it affects” is invalid. *Romer v. Evans*, 517 U.S. 620, 632 (1996).

But even assuming strict scrutiny applies, Plaintiffs rely on a misreading of *Regents of the Univ. of Cal. v. DHS*, 140 S. Ct. 1891, 1916 (2020). ECF No. 27 at 42. Plaintiffs may not bypass *Regents'* contemporaneous statement requirement just because a relevant actor's statement is involved. 140 S. Ct. at 1916. *Regents* establishes that a plaintiff must plead both “contemporary statements” that are made by “[t]he relevant actors.” *See id.* And even if Plaintiffs had met those requirements, the cited statements do not reflect animus. ECF No. 22 at 34-35.

Finally, dismissal now would not be premature, *see* ECF No. 27 at 42-43, as Plaintiffs have not met their burden to state an equal protection claim in the Amended Complaint. *See Ashcroft v. Iqbal*, 556 U.S. 662, 677-83 (2009). Plaintiffs cannot leap over this threshold requirement based on pure speculation that the administrative record might support their claim. *See id.*

B. HHS's Enforcement Policy is not Reviewable Final Agency Action

Plaintiffs argue that they have met the *Bennett* test based only on statements in the regulation's preamble, but as explained *supra*, at 8-9, a preamble is not binding, so nothing included in one is an action meeting either prong of the *Bennett* test. *See Bennett v. Spear*, 520 U.S. 154, 178 (1997); *see Ctr. for Auto Safety v. NHTSA*, 452 F.3d 798, 808 (D.C. Cir. 2006)

(second half of *Bennett* test failed when policy has “not been published in the Code of Federal Regulations”); *Crowley Caribbean Transp., Inc. v. Pena*, 37 F.3d 671, 677 (D.C. Cir. 1994) (policy unreviewable because it was not a “binding expression of agency viewpoint”). Unlike the policies courts found reviewable in the cases Plaintiffs cite, it makes no sense to conclude that a purported policy located only in the preamble to a binding regulation is itself binding; if the agency had intended the policy to be binding, it would have included it in the regulation itself. What is more, “[t]he language used by an agency is an important consideration,” *Ctr. for Auto Safety*, 452 F.3d at 806, and Plaintiffs’ only response to the preamble’s qualification is that the “statement cannot bear the weight Defendants pile atop it” because it is a “single sentence.” ECF No. 27 at 44. Of course, Plaintiffs cite no support for the idea that the quantity of words used to convey a qualification bears any relation to its meaning. Indeed, the cases Plaintiffs cite in support of reviewability are premised on an *unqualified* official pronouncement. *See, e.g., OSG Bulk Ship, Inc. v. United States*, 132 F.3d 808, 811-12 (D.C. Cir. 1998); *Edison Elec. Inst. v. EPA*, 996 F.2d 326, 333 (D.C. Cir. 1993). Plaintiffs’ reading is also premised on a misunderstanding of the timeline—HHS did *not* “publish[] its rule, and this sentence *after Bostock*.” ECF No. 27 at 44. “[T]he Rule was finalized within HHS on May 20, 2020, and was filed [with the Office of the Federal Register] on June 12, 2020.” *Washington*, 2020 WL 5095467, at *3 n.5. By the time the Office of the Federal Register published the rule, the 2020 Rule and the preamble were already published on HHS’s website.¹²

In any event, Plaintiffs’ arguments in Count IV are premised only on their interests in enforcement actions that “OCR will [or will] not take administrative[ly,]” ECF No. 27 at 43, but “a private citizen lacks a judicially cognizable interest in the prosecution or nonprosecution of another.” *Diamond*, 476 U.S. at 64 (quoting *Linda R.S.*, 410 U.S. at 619).

¹² Plaintiffs find no support in *OSG Bulk Ships, Inc. v. United States*, 132 F.3d 808, 812 (D.C. Cir. 1998), where the agency “[n]otably” did not press the argument that the policy was unreviewable, *see id.* at 812 n.6, and the case involved a “longstanding interpretation” of a statute, *id.* at 809.

CONCLUSION

For the foregoing reasons, this Court should dismiss the Amended Complaint.

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